UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968
Case No.: 2:08-md-1968

THIS DOCUMENT RELATES TOALL CASES AND SPECIFICALLY:
Case No. 2:09-cv-0671
Case No. 2:09-cv-0768

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL LIABILITY EXPERTS

I. INTRODUCTION

Plaintiffs in the matter of *Kathy McCornack, et al. v. Actavis, et al*., Case No. 2:09-cv-0671, ("*McCornack* Plaintiffs") and *Scottie Vega, individually and as next friend of Christopher Vega, a minor and surviving nature child of Mimi Rivera-Vega v. Actavis, et al*, Case No. 2:09-cv-0768 ("*Vega* Plaintiff") , hereby respectfully submit the following:

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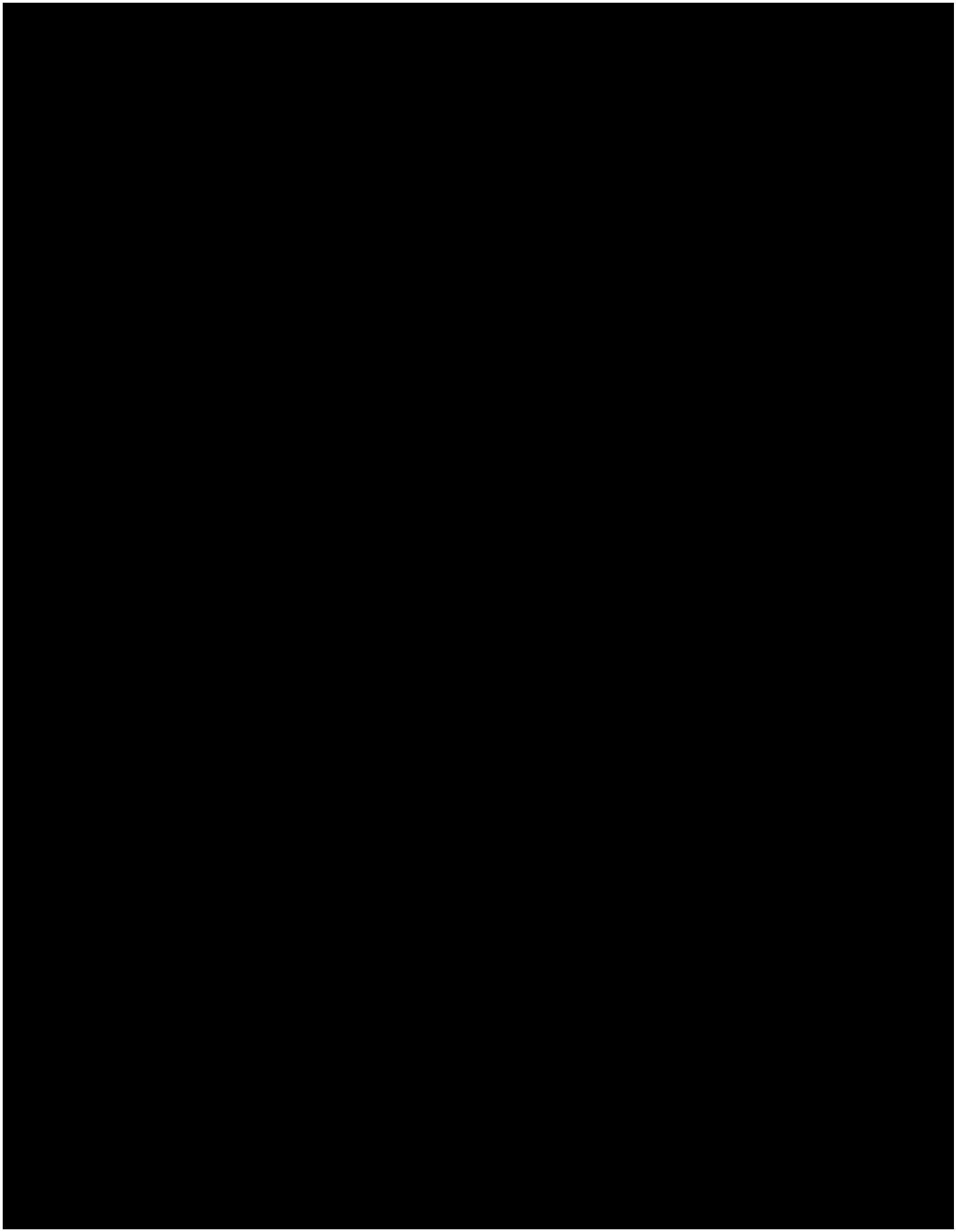
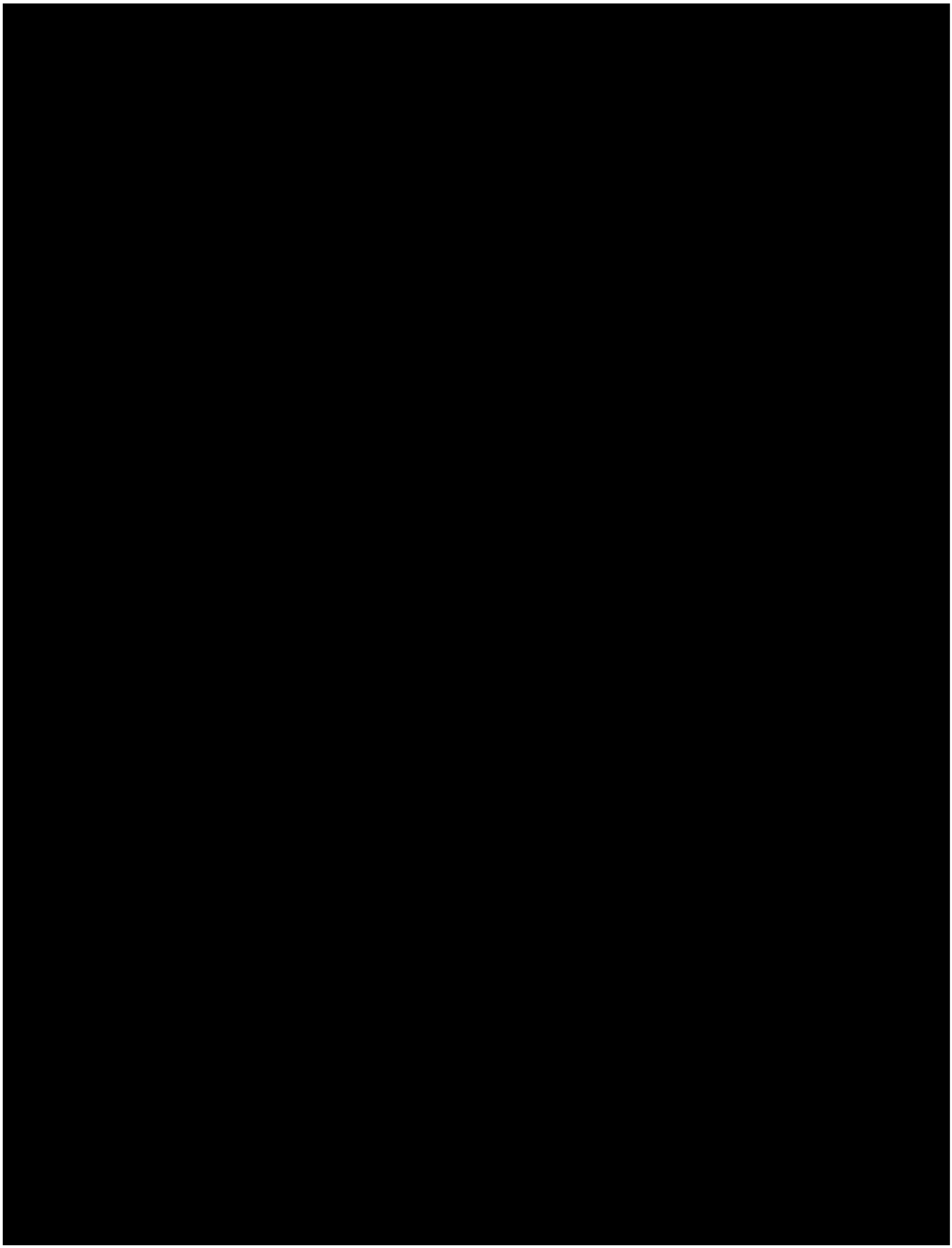
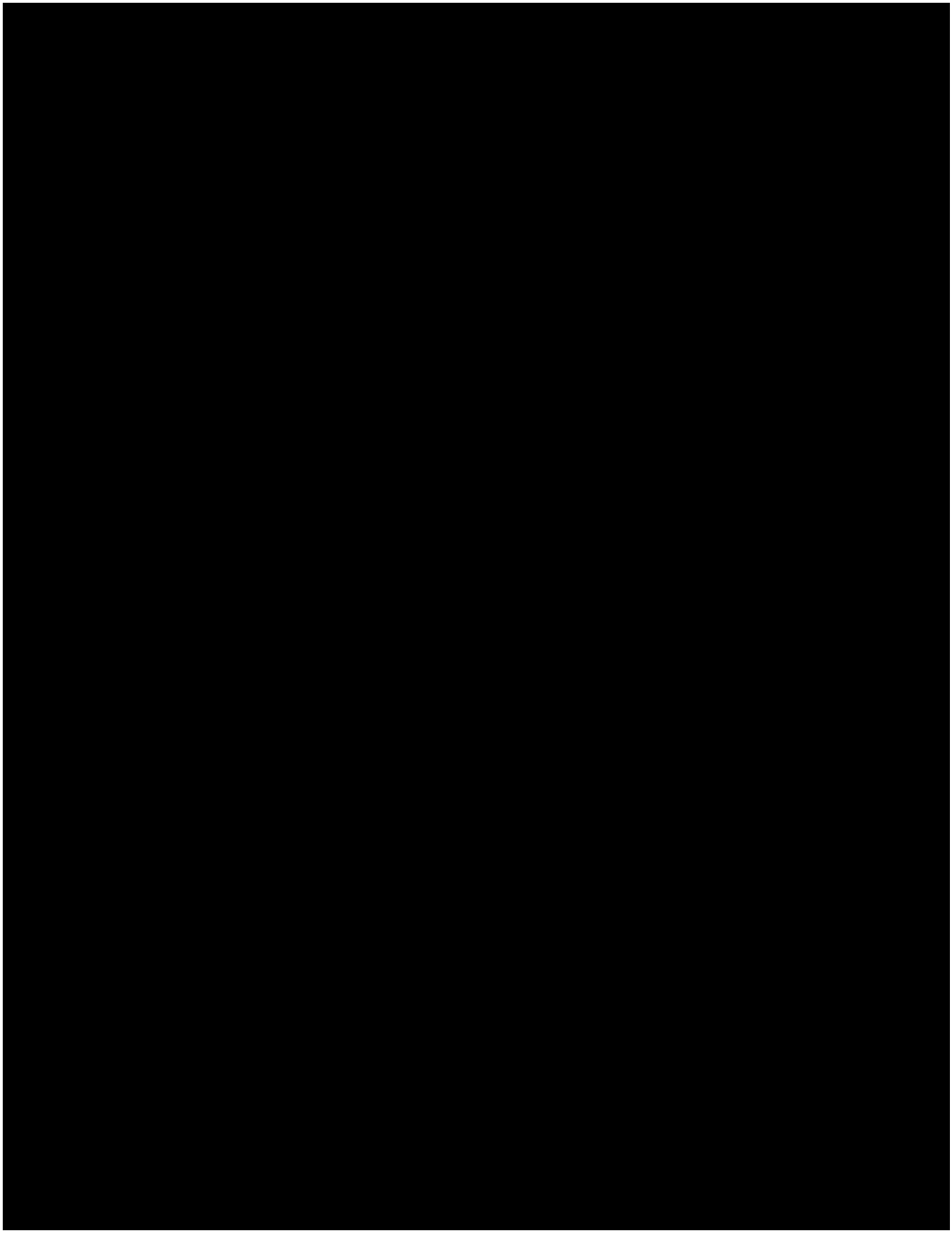
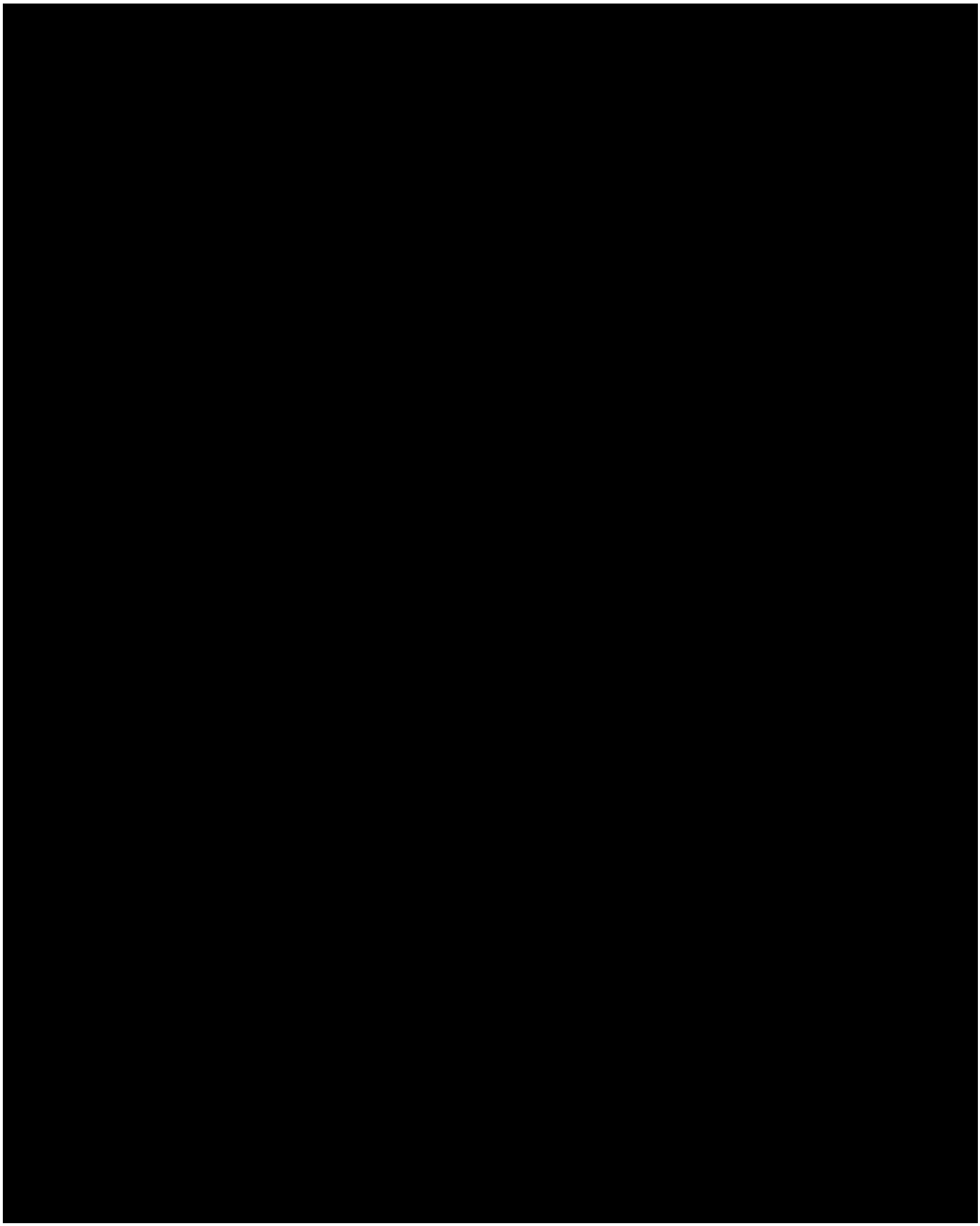






Dr. Bliesner, a respected expert concerning Current Good Manufacturing Practice ("CGMP") and Quality Safety Regulations compliance for the pharmaceutical industry, reviewed the foregoing history (and numerous other similar reports). He concludes that Actavis (and its



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Pl. Ex. 500, (A37). On April 24-25, 2008, Actavis instituted a nationwide recall of all Digitek.

[redacted]

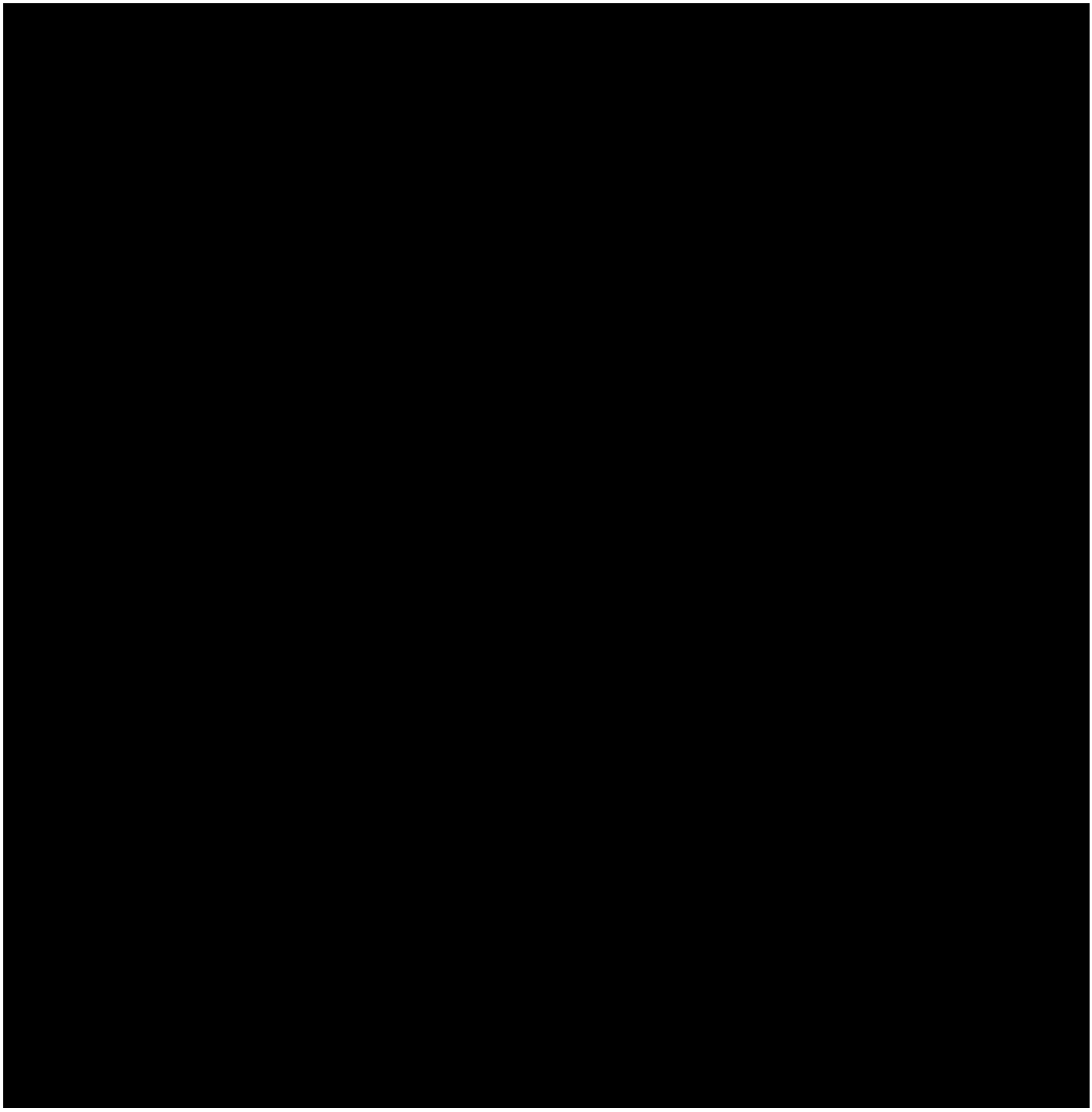
The consumer-level recall notice mailed to pharmacy retailers dated May 2, 2008, less than two months after his death, similarly advised:

> On April 25, 2008, Actavis Totowa LLC, the manufacturer of Digitek 0.125 mg and Digitek 0.25 mg tablets, issued a Patient Level Recall of all lots of these products as a precaution **because the tablets may be double the appropriate thickness and could contain twice the approved level of active ingredient**. Because of this, the manufacturer is recalling all lots of these products.

Pl. Ex. 506, (Bates 1222, *emphasis in original*).

II. ARGUMENT

A. Plaintiffs Didn't Find What Actives Never Looked For.



B. Plaintiffs' Quality Control Experts Methodology is Sound

1. Dr. David Bliesner

Dr. David Bliesner is a Ph.D chemist who consults with the pharmaceutical industry. Dr. Bliesner has prepared a declaration responding to the unfounded criticisms of his opinions and their basis. (Pl. Ex. 500, Bliesner Declaration Pl. Ex 620) In general, the Defendants set up the

classic straw man argument in their criticism of Dr. Bliesner. They impose upon Dr. Bliesner (and all of Plaintiffs' defect experts), an inapplicable standard and then criticize these professionals for not meeting that standard. In the case of Dr. Bliesner, Defendants questioned him extensively regarding projects he has done for his pharmaceutical clients. The projects Dr. Bliesner did for his private clients, that the Defendants questioned him about in his deposition, are different than the analysis he did in this case. (Pl. Ex.500, Bliesner Declaration Pl.Ex. 620) As explained in Dr. Bliesner's declaration, he performed an analysis of the "Quality Systems" at the Defendants' manufacturing facilities. *Id.* Quality Systems is a component of the product delivery system of any pharmaceutical company. *Id.* The integrity and actual performance of a company's Quality Systems is the measure of how well a company will be able to adhere to good manufacturing practices. *Id.* The actual performance of a company's Quality Systems tell us whether they have the appropriate processes and personnel in place to detect defective products and prevent them from reaching the consuming public. *Id.* Dr. Bliesner did not do and could not have done a full systems audit of the Defendant's manufacturing facility. *Id.* To do that type of consulting project, necessitates the full cooperation of the client, unfettered by the limitations and limited scope of legal discovery. *Id.* Dr. Bliesner performed an analysis of the quality and integrity of the Quality Systems, also known as Quality Assurance, program of the Defendant. *Id.* As explained by Dr. Bliesner, the Quality Systems program is the last line of defense that protects the consuming public from being exposed to defective products in the market place. *Id.* This type of analysis is customary in the industry. *Id.* This is the type of work that Dr. Bliesner does for his clients. *Id.* He is qualified to make this judgment. *Id.* It is the most relevant analysis in answering the question: Did defective Digitek tablets make it past the Defendants' manufacturing and inspection personnel and into the market place? *Id.*

Dr. Bliesner did an extensive analysis of the performance of the Defendant's Quality Systems. (Pl. Ex.500, Bliesner Report and Bliesner Declaration Pl. Ex. 620) The documentation he reviewed is set out in detail in his report. *Id.* Both the facts and the documents supporting the facts set out above were all part of Dr. Bliesner's data base and analysis. *Id.* The measure of the performance of a company's Quality Systems is found in what they do when something goes wrong. *Id.* Good Manufacturing Practices (GMP) is designed to consistently produce products within specification. The GMPs are validated and approved by the FDA. This case is not about whether or not the Defendants followed proper manufacturing processes. It is a given that they

[redacted]

This is the type of analysis that Dr. Bliesner did in this case. *Id.* He reviewed the performance of the Quality Systems of the Defendant. *Id.* He did this by looking at the most telling evidence of whether or not this last line of defense was solid or porous. He looked at evidence that told the story of how the Quality Systems have worked in the past. *Id.*

Defendants would like to limit this inquiry to just mistakes they made in the manufacture of Digitek. This would be an artificial and misleading limitation on this sort of inquiry and intellectually dishonest. Such a limitation would make any examination of a company's ability to adhere to its Quality Systems logically flawed. Quality Systems apply to all products. *Id.* There is not one Quality System for Digitek and another for other individual products manufactured by the Defendant. Any instance of a breakdown in the Quality System at a company, no matter what the product or where in the manufacturing process it occurs, is indicative of the integrity of the whole system. Any system in a company has a failure rate. Nothing is perfect and no company Quality System performs perfectly. However, there comes a point that a company's track record of repeated failures in the performance of a Quality System passes the threshold from less than perfect to failure. *Id.* Dr. Bliesner has the expertise to make that call. *Id.* He has worked in the industry for many years. *Id.* He has done this type of review for his clients. *Id.* He has participated in the Quality Systems of companies as a chemist. *Id.* Further, Dr. Bliesner has the necessary information to make this call in this case. He has reviewed extensive documents and instances as set out in his report of repeated Quality Systems failures in Defendants' facilities. *Id.* At some point in time, more evidence of failure is just cumulative in terms of expressing a competent opinion about whether or not the Quality Systems of a company has

experienced a melt down and is ineffective. Dr. Bliesner has the expertise to know when that threshold has been reached and he has expressed the opinion that he has seen more than enough evidence to support his opinion that the Defendants had suffered a long term, chronic, substantial and sometimes, total failure of their Quality Systems. *Id.*

The inferential leap, that a failure of the last line of defense in protecting the consuming public from the Defendants' defective products probably did result in defective Digitek reaching the market, is not long. The critical importance of supported, comprehensive and fully operational Quality Systems is carefully explained in both Dr. Bliesner's report and his declaration. (Pl. Exs. 500, 620, Bliesner Report and Declaration Pl. Ex. 620). When this safeguard is impaired or is failing on a regular basis, the likelihood of defective product slipping through the cracks in the failed system is substantially increased. *Id.* The greater the dysfunction of the Quality Systems, the greater the probability that defective product will slip through and be packed. *Id.* Dr. Bliesner's opinion, based on his extensive review of the Defendants' track record, is that this company had virtually no safety net, no barriers, no reliable redundancy, and therefore little or no chance to detect and prevent the release to the consuming public of the defective Digitek that they made. In fact, any argument that they performed differently than their track record reflects, is less than plausible.

2. Plaintiffs' Experts Farley, Kenny and Somma

Plaintiffs' experts Farley, Kenny and Somma have performed essentially the same analysis as Dr. Bliesner. They looked at the same documents and have been criticized by the Defendants in the same manner as Dr. Bliesner. The Defendants set up the straw man argument and then attack the straw man. The Defendants never directly deal with the meat of all these experts' opinions in their motion to strike. They are all qualified professionals with extensive

experience in the pharmaceutical industry. They know how to call a ball and strike when it comes to evaluating whether or not a company has adequate systems in place to prevent defective product from reaching the hospitals, pharmacies and homes of patients who need this medicine. They all understand that out of specification, Digitek that is double thick and double strength, poses as serious risk to the patients who take this medicine. The Defendants know this too. They all have weighed this risk against the paltry efforts by the Defendants to do what a reasonable manufacturer would do to set up quality assurance systems so that if and when something goes wrong, the proper procedures are in place and followed to prevent defective product from reaching the market place. They have all reached the same conclusion; because the Defendants' quality systems were in such disarray, it is more likely than not that defective Digitek reached the market place. Actavis was just not capable enough to have caught all the bad tablets. (Pl. Exs. 514, 511, 516, Reports of Farley, Kenny and Somma)

III. Objection to Defendants Motion to Strike and Brief in Support.

This Court's local rules limit motions of the type filed by the Defendants in this case to 20 pages. Defendants did not seek leave of Court to exceed this limit. Plaintiffs move to strike the motions in their entirety or in the alternative, strike all pages in excess of 20 pages.

IV. Conclusion

The Defendants' arguments simply miss the point. They argue that Plaintiffs' experts should have reviewed documents that are not relevant to the opinions they express. They argue that Plaintiffs should have performed a different type of analysis, unrelated to the core questions in this case, and since they didn't, their opinions are not valid. Most telling is the fact that the Defendants do not directly attack the meat of the Plaintiffs' experts' opinions. They do not attack, because it is undeniable. This Defendant had a long and chronic history of poor quality

assurance systems performance that serves as the basis for these experts' opinions. Nor do they attack the inescapable logic that a company with an extremely poor performance record of quality assurance probably did not have the capacity to detect all the defective Digitek they made and prevent exposure to the consuming public. The Defendants' motion should be denied in all things and this case set for trial.

Respectfully Submitted:

Dated: August 24, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2011, a copy of the Response to Defendants' Motion to Exclude Plaintiffs' General Liability Experts was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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